510(k) SUMMARY

NOV 6 2002

DENTSPLY

NAME & ADDRESS:

K023697

DENTSPLY International
570 West College Avenue
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York, PA 17405-0872
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CONTACT: P. Jeffery Lehn

DATE PREPARED: October 30, 2002

TRADE OR PROPRIETARY NAME: JET-MATE™ STERILIZABLE HANDPIECE

CLASSIFICATION NAME: Accessory to dental units (872.4850 and 872.6080)

PREDICATE DEVICES: Steri-Mate™ Handpiece K941392

DESCRIPTION OF DEVICE: The Jet-Mate™ Sterilizable Handpiece is a detachable dental handpiece. It is designed to be detached from the cable assembly for the purpose of autoclave sterilization. This modified handpiece is used with the Cavitron® dental units.

INTENDED USE: The Jet-Mate™ Sterilizable Handpiece is designed for general prophylaxis treatments to remove calculus, plaque and stains from teeth

TECHNOLOGICAL CHARACTERISTICS: The Jet-Mate™ Sterilizable Handpiece has the same principles of operation and is very similar in design characteristics to the marketed device. Therefore, we believe that the Jet-Mate™ Sterilizable Handpiece is substantially equivalent to the Steri-Mate® Handpiece (K941392).

Because of the nearly equivalent material composition of JET-MATE™ STERILIZABLE HANDPIECE to the predicate device, no additional toxicity testing was necessary.

We believe that the prior use of the components of JET-MATE™ STERILIZABLE HANDPIECE in legally marketed devices and the data provided support the safety and effectiveness of JET-MATE™ STERILIZABLE HANDPIECE for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 2002

Mr. P. Jeffery Lehn
Director, Compliance and Regulatory Affairs
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K023697
Trade/Device Name: Jet-Mate™ Sterilizable Handpiece
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: 76 ELC
Dated: October 30, 2002
Received: November 4, 2002

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K023697

Device Name: **Jet-Mate™ Sterilizable Handpiece**

Designed for use in general prophylaxis and periodontal treatments and other areas of operative dentistry for the supragingival and subgingival removal of calculus, plaque and stains from teeth.

This is the same intended use as previously cleared for K941392, Steri-Mate™ Handpiece.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023697